

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
GROUP ART UNIT 3767**

EXAMINER: Elizabeth MacNeill
APPELLANT: Gin Wu
SERIAL NO: 10/662,744
FILED: September 15, 2003
FOR: Hard Tissue Drug Delivery Device and Method

Commissioner of Patents and Trademarks
Washington, D.C. 20231
Attention: Board of Patent Appeals and Interferences

APPELLANT'S REPLY BRIEF UNDER 37 CFR §41.41

This reply brief is filed in response to the Examiner's Answer mailed May 8, 2008. The Applicant respectfully requests that the appeal filed April 7, 2008 be maintained under 37 CFR 41.41.

ARGUMENT

A. REJECTION OF DE SANTIS CLAIMS 14, 15, 17, 18, 22, AND 23 UNDER 35 U.S.C. 102(B) AS BEING ANTICIPATED BY DE SANTIS

The Office's rejection claims 14, 15, 17, 18, 22, and 23 under 35 U.S.C. 102(b) as being anticipated by De Santis (US 5,560,373) should be withdrawn.

As discussed in the opening brief, anticipation under 35 U.S.C. § 102 requires the presence in a single prior art disclosure of each and every element of a claimed invention. [citations omitted], and during examination proceedings, claims are given their broadest reasonable interpretation consistent with the specification. [citations omitted].

The Office argued that, while De Santis fails to teach that the overall length of the notch is greater than the thickness of the tissue, the De Santis device could be used on extremely thin bones to satisfy this limitation. The Applicant disagrees. Since the device taught by De Santis is

“specifically designed to allow the physician user to extract a sample of tissue,” (See C2/L37-39) the device in De Santis could not be used on extremely thin bones, as the examiner suggests. The device in De Santis must be used in tissue where the vacuum force can draw the cut tissue into the biopsy reservoir. (See De Santis, C10/L10-15)

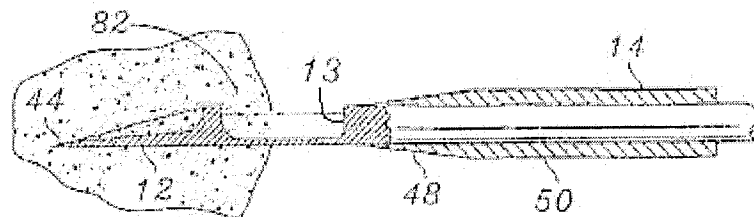
Furthermore, even if De Santis were to be used in thin hard tissue to satisfy the limitation:

“wherein an overall length from a distal tip of the cutting surface to a proximal end of the open notch is greater than a thickness of the hard tissue,”

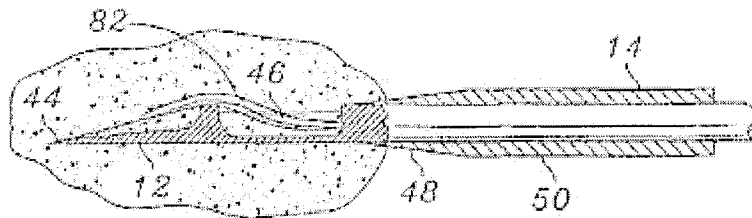
then such use would fail to satisfy another of the limitations:

“a lumen inside the shaft that extends between first and second openings, and that receives debris entering the first opening as a result of operation of the cutting surface.”

This can be readily appreciated by consideration of the images below. If De Santis were to be used on thin tissue, where the overall length from the distal tip of the cutting surface to the proximal end of the open notch, the tissue **82** would be nowhere near the lumen **13**, and the lumen could not “receive debris entering the first opening as a result of operation of the cutting surface.”



The lumen of the device taught in De Santis *could* “receive debris entering the first opening as a result of operation of the cutting surface” if the tissue were thicker, as taught in C10/L2-14 and corresponding Figure 12a. However, as pictured below, if the device taught in De Santis were to be used in such thicker tissue, then the overall length between the distal tip of the cutting surface to the proximal end of the open notch would be less than the thickness of the hard tissue.



Additionally, the Office argues that De Santis is capable of injecting a medication as claimed in the preamble of claim 14 and the body of claim 19. However, as one of ordinary skill in the art would appreciate from the figure above, the lumen 13 would be clogged with tissue and injecting medication would be extremely difficult if not impossible. The current invention is, in fact, designed to overcome this very problem of the lumen becoming clogged. (See Specification, P3/L5-9).

B. REJECTION OF CLAIMS 14, 15, 17, 19 AND 21 AS BEING ANTICIPATED BY SHAW

The Office’s rejection of claims 14, 15, 17, 19 and 21 under 35 U.S.C. 102(b) as being anticipated by Shaw (US 5,261,818) should also be withdrawn.

“A fundamental principle contained in 35 U.S.C. 112, second paragraph is that applicants are their own lexicographers. They can define in the claims what they regard as their invention essentially in whatever terms they choose so long as any special meaning assigned to a term is clearly set forth in the specification.” (See MPEP 2173.01). “An inventor may define specific terms used to describe invention, but must do so ‘with reasonable clarity, deliberateness, and

precision” (See MPEP 2111.11) In our case, the specification defined the term “open notch” to mean “a small hole through the wall of the hollow drill” through the use of a parenthetical appositive.

“An alternative design of this invention is a hollow drill bit with an open notch (a small hole through the wall of the hollow drill) located proximal of the distal beveled tip.” (See Specification, P4/L1-3)

Parentheses are used to “enclose words, phrases, clauses, and sentences as explanations or commentary.” See The Grammar Bible at 437, by Michael Strupf and Auriel Douglas. An appositive is a “word, phrase, or clause that is placed beside another word to rename, explain, or enhance it.” See Id at 30-31. Here, the use of a parenthetical appositive is known to be a deliberate way of clearly defining and explaining a particular term so that a person of ordinary skill in the art would know what that term means. The Office disagrees, but cites no support for its argument.

The Office also argues that even if the term “open notch” were defined as suggested by the Applicant, the device of Shaw meets this limitation by providing flutes and bores (See Shaw C2/L50 and corresponding Figures 3-5). That argument, however, is defective because the Office is forced to equate the flutes 26 and bores 24 of Shaw to the “small hole[s] through the wall of the hollow drill” of the pending application. That doesn't make sense because in the present context, a hole means something that pass through a wall. Shaw's flutes and bores are not holes because they do not go through the wall of Shaw's drill bit. The Office argues that a "hole" such as a hole in the ground, need not extend through anything. But that argument ignores the Applicants definition of "a small hole through the wall of the hollow drill".

C. REJECTION OF CLAIM 16 AS BEING OBVIOUS OVER SHAW

The Office's obviousness rejections of claims 16 and 20 under 35 U.S.C. 103(a) should also be withdrawn.

The Applicant previously argued that claims 16 and 20 are dependent in one way or another on independent claim 14, and since Shaw clearly does not teach, disclose or even suggest

claim 14 from the reasons discussed above, Shaw also cannot be seen to teach, disclose or even suggest the elements of claims 16 and 20.

The Office argued that since the device of Shaw is designed for use in the mouth, there are certain “inherent limitations” that are required for maneuverability and ease of use. The Office seems to be implying that the drill bit of Shaw would inherently have an overall length of about 0.10 to 0.125 inches (2.54 mm to 3.175 mm) to be properly used and to be maneuverable in a mouth. The Applicant respectfully disagrees because such lengths are inconsistent with Shaw's disclosure. Shaw's drill bit must have a length of at least 12 mm because the last serration is stated to be at least twelve mm from the tip. (See C2/L65-C3/L1). Additionally, one of the objects of Shaw is “to provide an improved irrigation drill having particular utility in creating precise depth and diameter of bores in jawbones at sites of dental implant insertion.” (C1/L57-60). A person of ordinary skill in the art would not attempt to create a drill bit for a jawbone that is only 0.10 to 0.125 inches long. Such a drill would not be long enough to carry out normal dental operations.

As an aside, it is also fascinating that the Office would feel free to find inherent limitations on the applicant's drill bit when it refused to accept limitations on the term "open notch" that were expressly stated as an appositive in the specification.

Request for Allowance

Claims 14-23 are pending in this application. The Applicant believes that the current pending claims are allowable because independent claim 14, upon which claims 15-23 depend, recites limitations that both De Santis and Shaw fail to teach, motivate, or suggest. The Applicant requests allowance of all pending claims.

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Respectfully Submitted,
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